

First successful traditional-use registration for a product containing St John's Wort and Valerian

Oldenburg (DE), Münster (DE), 26. September 2016 – The pharmaceutical service provider Diapharm has succeeded in obtaining traditional-use registration for a combination product containing St John's Wort and Valerian extracts for the treatment of mental exhaustion (fatigue) and related sleep disturbance. Until now, the time-consuming marketing authorisation process was the only path to being able to market products containing St John's Wort and Valerian. For the first time, Diapharm has been able to register with the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) a combination product consisting of both active pharmaceutical ingredients (APIs) with an appealing indication and a consumer-friendly dosage. The combination product is available for licensing.

“The combination of traditionally used herbal APIs is a valuable opportunity for advancement in this market segment,” said Dr Rainer Kolkmann, Head of Product Development at Diapharm. “By registering interesting combination products, we are paving the way to making traditional herbal active pharmaceutical ingredients interesting for the market again.”

Just a few weeks ago, Diapharm and one of its clients obtained decentralised procedure (DCP) registration in seven EU countries for the combination of St John's wort and black cohosh for relieving the symptoms associated with menopause. The company has helped manage over 500 medicinal product registrations and marketing authorisation processes for phytopharmaceuticals throughout Europe.

(approx. 1.570 characters)

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*Press releases from Diapharm and photo material in print quality may be downloaded from:
www.diapharm.com/pr.html*

Photo caption (Hypericum_Valeriana_DIAPHARM.jpg)

Diapharm has obtained traditional-use registration for a combination containing St John's wort and valerian extracts for the treatment of mental exhaustion and associated insomnia.

Background information: Diapharm GmbH & Co. KG

Diapharm (www.diapharm.com) is a leading global consulting firm and service provider for the consumer healthcare and pharmaceutical industry. Founded in 1988, Diapharm supports clients in the fields of medicinal products, medical devices, food supplements, dietetic foods and cosmetics. Its work focuses on regulatory affairs and marketing authorisation, medical and scientific tasks, quality assurance and consulting. With around 100 employees in Germany, the United Kingdom, Austria and China, Diapharm supports multinational corporations, recent start-ups and medium-sized companies.